IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC., REBIOTIX INC. Plaintiffs, v. FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., and FINCH THERAPEUTICS HOLDINGS, LLC. Defendants.	C.A. No. 21-1694-JLH Redacted Version of D.I. 279
FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., FINCH THERAPEUTICS HOLDINGS, LLC, and REGENTS OF THE UNIVERSITY OF MINNESOTA Counterclaim-Plaintiffs/Reply Defendants, v. FERRING PHARMACEUTICALS INC., and REBIOTIX, INC. Counterclaim-Defendants/Reply Plaintiffs.	

FERRING/REBIOTIX'S OPPOSITION TO FINCH/UMN'S MOTION FOR SUMMARY JUDGMENT AND MOTION TO EXCLUDE KURT KARST'S EXPERT OPINIONS

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I. INTRODUCTION

Finch/UMN's Motion for Summary Judgment Against Ferring/Rebiotix's Fifth Affirmative Defense of Equitable Estoppel ("Summary Judgment Motion") (D.I. 259) should be denied. A reasonable fact finder could conclude, based on the record evidence, that Ferring/Rebiotix have met their burden to show that all three equitable estoppel elements are met as to the UMN Patents. Ferring/Rebiotix is not asserting an equitable estoppel defense for the Borody patents, so that portion of the Summary Judgment Motion should be denied as moot.

Moreover, Finch/UMN's Summary Judgment Motion is larded with irrelevant factual allegations that have nothing whatsoever to do with the merits of its motion—this is confirmed by Finch/UMN's failure to address any of those factual allegations in the body of its arguments.

Finch/UMN's Motion to Exclude Kurt Karst's Expert Opinions ("*Daubert* Motion") (D.I. 261) should likewise be denied. It is based on a false premise—that only a technical witness can provide expert testimony. Ferring/Rebiotix's expert Kurt R. Karst offers specialized knowledge in FDA practices and the impact of FDA decisions regarding drug approval and labeling. Mr. Karst's testimony on similar topics has repeatedly been allowed; he has never been excluded.

II. NATURE AND STAGE OF THE PROCEEDINGS

Plaintiffs Ferring Pharmaceuticals Inc. ("Ferring") and Rebiotix Inc. ("Rebiotix") (collectively, "Ferring/Rebiotix") filed this action against Finch Therapeutics Group, Inc., Finch Therapeutics, Inc., and Finch Therapeutics Holdings, LLC (collectively, "Finch") on December 1, 2021, seeking a declaration that seven patents naming Thomas Borody as the inventor and purportedly assigned to Finch ("Borody patents") are invalid or not infringed by Ferring's REBYOTA drug product. (D.I. 1.)

During the litigation, and [redacted]

[redacted] (Ex. A[1]), Finch amended its counterclaims to add UMN to the litigation and assert the UMN patents (D.I. 19). Ferring replied to the amended counterclaims on April 4, 2022 and asserted counterclaims in reply, including a sixth affirmative defense that Finch/UMN were estopped from asserting the counterclaim patents. (D.I. 30 at 66.) Finch/UMN subsequently filed second amended counterclaims on January 23, 2023. (D.I. 98.) In their reply on February 7, 2023, Ferring/Rebiotix asserted this estoppel defense as their fifth affirmative defense. (D.I. 126 at 101.)

Fact and expert discovery is complete and a five day jury trial is scheduled to begin on May 20, 2023.

On July 6, 2023, Ferring/Rebiotix filed a motion to dismiss the Borody patents for lack of standing. (D.I. 208.) The motion is fully briefed. (D.I. 209, 221, 232.) Both parties have requested oral argument. (D.I. 234, 238.) The Court referred the motion to then Magistrate Judge Hall on October 4, 2023. The motion is still pending and no argument has been scheduled. Because standing is a threshold jurisdictional issue, it must be resolved before the Court can consider any issues on the merits, including the issues raised in section III of this brief. *Media Techs. Licensing, LLC v. Upper Deck Co.*, 334 F.3d 1366, 1369 (Fed. Cir. 2003); *Wayne Land & Mineral Grp., LLC v. Del. River Basin Comm'n*, 959 F.3d 569, 574 (3d Cir. 2020).

[1] References to Ex. without an introductory D.I. number refer to the exhibits in the Declaration of Daniel M. Attaway in Support of Ferring/Rebiotix's Opposition to Finch/UMN's Motion for Summary Judgment and Motion to Exclude Kurt Karst's Expert Opinions, filed concurrently.

III. THE COURT SHOULD DENY FINCH/UMN'S SUMMARY JUDGMENT MOTION

A. Summary of Argument

This Court should deny Finch/UMN's Summary Judgment Motion because (i) Ferring/Rebiotix are not asserting an equitable estoppel defense against the Borody patents, making that portion of the motion moot, and (ii) a reasonable fact finder could determine that Finch/UMN are equitably estopped from asserting the UMN patents.

Finch/UMN assert that because UMN never "told" Ferring/Rebiotix they could "use" the UMN patents, there can be no equitable estoppel. (D.I. 262 at 9-10.) But that mischaracterizes Ferring/Rebiotix's position and is incorrect. Based on the facts in the record, a reasonable fact finder could determine that UMN, through its actions, inaction, and silence, reasonably led Ferring/Rebiotix to infer that UMN would not assert the UMN patents against Ferring/Rebiotix, that Ferring/Rebiotix relied on that inference, and was prejudiced thereby. In particular, given the high cost of developing and getting approval for a pharmaceutical product in the United States, especially for a first-in-class product like REBYOTA, Ferring/Rebiotix would be prejudiced if Finch/UMN are allowed to continue asserting the UMN patents.

B. Statement of Facts

Finch/UMN's "Statement of Facts" contains three sections of alleged facts relevant to the Summary Judgment Motion. (D.I. 262 at 4-8.) Tellingly, however, Finch/UMN's argument does not rely on (or even mention) most of the facts Finch/UMN recite, and many of the "facts" included in Finch/UMN's argument do not appear in their "Statement of Facts." (*Compare id.* with D.I. 262 at 9-19.) Indeed, the first two sections of Finch/UMN's "Statement of Facts" have nothing to do with the elements of Ferring/Rebiotix's equitable estoppel defense. Instead, these facts pertain to their allegations of copying and willfulness—which are not the subject of Finch/UMN's Summary Judgment Motion (D.I. 259), but which are addressed in

Ferring/Rebiotix's Motions for Summary Judgment (D.I. 256, ¶ 1) and related briefing (D.I. 258 at 3-7).

Further, Section A of Finch/UMN's "Statement of Facts" is essentially unsupported by evidentiary citations. (D.I. 262 at 4.) Instead, the section contains argument characterizing Finch/UMN's alleged inventions, the scope of those inventions, and the interplay between the Borody patents and UMN patents. (*Id.*) The Court should disregard these factual allegations because Finch/UMN has failed to support them. FED. R. CIV. P. 56(e); *see White v. Atkore Corp.*, No. 16-1422, 2018 WL 2688434, at *1 n.4 (E.D. Pa. June 4, 2018) (disregarding unsupported facts set forth in summary judgment brief).

Similarly, Section B is not germane to the issue of equitable estoppel—instead focusing on Finch/UMN's allegations of copying and willful infringement. (D.I. 262 at 5-6.) They are addressed, more properly, in Ferring/Rebiotix's motion for summary judgment of no copying and no willfulness. (*Compare id. with* D.I. 258 at 3-5.) These facts are not relevant to (or even referenced in) Finch/UMN's argument

C. Legal Standards

Ferring/Rebiotix does not dispute the generalized statement of legal standards set forth by Finch/UMN in Sections IV.A and IV.B of its brief in support of the Summary Judgment Motion. (D.I. 262 at 8-9.)

D. Argument

1. The Court should deny as moot the Summary Judgment Motion with respect to the Borody patents

Finch/UMN's Summary Judgment Motion (D.I. 259) appears to misapprehend Ferring/Rebiotix's equitable estoppel defense. Specifically, Ferring/Rebiotix's final objections and response to Finch/UMN's Interrogatory No. 7 make clear that Ferring/Rebiotix are only

asserting that Finch/UMN are equitably estopped from asserting the UMN patents. (D.I. 265, Ex. 23 at 35-41.) For example, Ferring/Rebiotix's final response on equitable estoppel begins by noting:

> To succeed on their equitable estoppel defense, Ferring/Rebiotix must show that:
>
> 1. **UMN**, through misleading conduct (e.g., statements made to individuals at Rebiotix or Ferring, action, inaction, or silence where there was an obligation to speak) led Ferring/Rebiotix to reasonably infer that **UMN** did not intend to assert infringement of the **UMN patents**;
>
> 2. Ferring/Rebiotix relied on **UMN's** misleading conduct; and
>
> 3. Because of Ferring/Rebiotix's reliance on **UMN's** misleading conduct, Ferring/Rebiotix will be materially prejudiced by allowing **UMN** to proceed with its claims.

(*Id.* at 35 (emphasis added).) Similarly, Ferring/Rebiotix's response ends by stating: "[A]t least for the reasons above, **UMN** is equitably estopped from asserting the **UMN patents**. (*Id.* at 41 (emphasis added).)

In other words, Ferring/Rebiotix have not, and do not assert the equitable estoppel defense as to the Borody patents. Accordingly, the Court should deny that portion of the Summary Judgment Motion as moot.

2. A reasonable fact finder could conclude that assertion of the UMN patents is barred by equitable estoppel

For the reasons discussed below, a reasonable fact finder could conclude that Ferring/Rebiotix can meet each of the three elements of Ferring/Rebiotix's equitable estoppel defense against the UMN patents.

a. A reasonable fact finder could conclude that UMN's course of conduct was misleading

First, Finch/UMN assert that "Ferring/Rebiotix provide no facts supporting" their assertion that "UMN, through misleading conduct (e.g., statements made to individuals at Rebiotix or Ferring, action, inaction, or silence where there was an obligation to speak) led Ferring/Rebiotix to reasonably infer that UMN did not intend to assert infringement of the UMN patents." (D.I. 262 at 9 (quoting D.I. 265, Ex. 23 at 35).) Finch/UMN's basis for this assertion is that no one at UMN ever explicitly stated to anyone at Rebiotix or Ferring that they "had permission to use UMN's technology or that UMN would not assert its patents." (D.I. 262 at 9-10.) Finch/UMN's position is not the law. To be sure, common ways to show estoppel are via an affirmative promise not to assert the patents, or even an affirmative assertion of alleged infringement followed by a period of silence. *See, e.g.*, *Radio Sys. Corp. v. Lalor*, 709 F.3d 1124, 1130-31 (Fed. Cir. 2013). But, as an equitable doctrine, estoppel is not so narrowly confined; courts must look at the facts as a whole and are not confined to "resolution by simple or hard and fast rules." *A.C. Aukerman Co. v. R.L. Chaides Const. Co.*, 960 F.2d 1020, 1041 (Fed. Cir. 1992) (en banc), *abrogated on other grounds by SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 580 U.S. 328 (2017); *see also High Point SARL v. Sprint Nextel Corp.*, 817 F.3d 1325, 1330 (Fed. Cir. 2016) (noting that silence, when coupled with other conduct, was sufficiently misleading to satisfy the first element of equitable estoppel).

Here, focusing in particular on UMN's course of conduct after the UMN patents began to issue in April 2019, a reasonable fact finder could determine that conduct misled Ferring/Rebiotix into believing that UMN would not assert the UMN patents against them.

During that time frame, UMN's actions and silence were sufficient for a reasonable fact finder to determine that it misled Ferring/Rebiotix into believing it would not assert the UMN

patents. For example, on June 21, 2019, Ms. Jones was an invited speaker at the CEMS[2] Centennial & Jubilee. Ex. B. The program was meant to "highlight notable alumni achievements." https://m.facebook.com/cemsumn/videos/772853733202757/?locale=ur_PK] (last visited Jan. 7, 2024). Ms. Jones's presentation at the Jubilee was on "Microbiome Research Entrepreneurship" and focused on her work at Rebiotix and the development and clinical testing of REBYOTA. *Id.*

Less than a year later, the Carson School of Management at the University of Minnesota awarded Ms. Jones the 2020 University of Minnesota Entrepreneur of the Year award. Ex. C; *see also* Ex. D. In the press release for the award, UMN specifically focused on Ms. Jones's work at Rebiotix and her continued involvement with UMN. *See* Ex. D at 1. For example, the May 20, 2020 press release includes the following:

> "You would be hard pressed to find anyone that has been more involved in supporting the entrepreneurial community at the University of Minnesota. Lee is the consummate role model for our students and alumni," noted John Stavig, director of the Gary S. Holmes Center for Entrepreneurship at the Carlson School of Management at the University of Minnesota.
>
> * * *
>
> Through her support in various University programs such as volunteering as an original MN Cup mentor, supporting the development of the Women's Entrepreneurship Program, serving as Chief Administrative Officer for the Schulze Diabetes Institute, advising the Technology Commercialization Office, and speaking regularly and mentoring students, Lee has generously giver her time to lead the entrepreneurial community in the Twin Cities.

Id. at 1.

[2] Department of Chemical Engineering and Materials Science at the University of Minnesota.

Further, in May 2021, Russ Straate, the Associate Director of the UMN Venture Center at the Office of Technology Commercialization ("OTC") reached out to Ms. Jones as part of a targeted search for a CEO for a new UMN spin-off. Ex. E. Mr. Straate had been involved with the OTC since Ms. Jones first volunteered as a CEO in Residence with the OTC in 2011 and had also been involved with the technology allegedly patented in the UMN patents. *See, e.g.*, Ex. F; *see also* Ex. G at 113:9-115:10. Mr. Straate explained that Ms. Jones was one of the individuals that he preselected to reach out to for potential names to fill this particular new CEO role. Ex. G at 245:12-22. Mr. Straate indicated that UMN expected the company would be "a top-tier UMN startup." Ex. E at UMN_0005765; *see also* Ex. G at 244:22-245:4. The product at issue was a diagnostic for lung cancer and had been spun out as Vocxi. Ex. G at 244:22-245:4, 246:18-247:14; *see also* Vocxi, http://vocxihealth.com (last accessed Jan. 2, 2024). Importantly, as part of the conversation, Mr. Straate specifically asked Ms. Jones if she would be interested in taking on the CEO role for the spinoff. Ex. E at UMN_0005764; Ex. G at 247:16-248:8.

Finally, in June of 2021, Courtney Jones was in touch with Pamela Johnson, Corporate and Foundation Relations at the University of Minnesota Foundation. Ex. H. Ms. Johnson informed Ms. Jones that she "met with Dr. Alex Khouruts [sic] to explore this [i.e., potential research collaboration] further. He shared with me that they recently launched a Microbiome Supergroup . . . ." *Id.* at FER_RBX01433984. As a result of the meeting with Ms. Johnson, Dr. Khoruts prepared a summary for Ms. Johnson to share with Rebiotix. *Id.* Importantly, that summary states, with respect to UMN's collaboration with Finch and the UMN patents:

> **UMN Microbiota Therapeutics Program.** This academic program is headed by Dr. Khoruts is well known to Rebiotix. It was the first to publish methods for standardized preparation of cryopreserved fecal microbiota and subsequently has developed a *freeze-dried, encapsulated preparation of fecal microbiota for oral administration (licensed by UMN to Finch Therapeutics).* For a

> number of years the program assisted Finch Therapeutics (and its precursors) in providing donor stool and development of GMP protocols for therapeutic microbiota preparation. *Since January of 2019 these collaborative relationships between Finch and UMN have ceased*, and the UMN Microbiota Therapeutics Program has continued to function independently with the mission of treating patients with *C. difficile* infections and supporting various early phase clinical trials for non-*C. difficile* indications.

Id. at FER_RBX01433989 (emphasis added). It would be reasonable to conclude, based on Dr. Khoruts's description that (i) only the freeze-dried capsule product is licensed to Finch (as opposed to an enema suspension like Ferring/Rebiotix's product) and (ii) Finch and UMN were no longer in a collaborative relationship such that any statements made by Finch concerning potential patent enforcement would not be applicable or attributable to UMN.

Considering these facts together, a reasonable fact finder could conclude that UMN's conduct led Ferring/Rebiotix to believe that UMN would not assert the UMN patents against them.

b. A reasonable fact finder could conclude that Ferring/Rebiotix relied on UMN's misleading conduct

Second, the record evidence shows that a reasonable fact finder could conclude that Ferring/Rebiotix reasonably relied on UMN's conduct after the UMN patents issued in April/May 2019 that UMN would not enforce the UMN patents. Finch/UMN's argument again centers on the fact that despite knowledge of the UMN patents, "Ferring/Rebiotix's corporate designee on Ferring's acquisition of Rebiotix, including any consideration of the Finch or UMN patents in connection with said acquisition, Greg Fluet, explicitly confirmed that Rebiotix did not think it had the right to use UMN's patents." (D.I. 262 at 16.) This testimony is off point for several reasons.

As an initial matter, the time frame and context of Mr. Fluet's testimony is wrong. As Finch/UMN admits, Mr. Fluet's corporate testimony extends only to "any consideration of the [] UMN patents in connection with [Ferring's] acquisition" of Rebiotix. (*Id.*) The merger agreement was consummated in March 2018, (D.I. 265, Ex. 31 at FER_RBX02738156), over a year before either of the UMN patents issued. Mr. Fluet's testimony is therefore irrelevant to whether Ferring/Rebiotix reasonably relied on actions that occurred after the UMN patents issued (like those discussed in section III.D.2.a above) to conclude that UMN would not enforce the UMN patents. The first part of Mr. Fluet's testimony is not merely too-narrowly focused on the "right to use" framing. (D.I. 262 at 16 (quoting D.I. 265, Ex. 21 at 70:12-71:6).) In addition, it specifically references the patent that issued from the '411 application. (D.I. 262 at 16 (quoting D.I. 265, Ex. 21 at 70:12-71:6); *see also* D.I. 265, Ex. 21 at 70:6-8 ("Q. Do you see Number 2 it says U.S. 14/003,411? A. Yes.").) But that patent—United States Patent Number 9,968,638 ("the '638 patent"), Ex. I—is not asserted in this litigation.

Further, an accused infringer like Ferring/Rebiotix can form a reasonable belief that it will not be sued in reliance on a variety of courses of conduct, including misdirection and silence. The formation of such a belief does not require Ferring/Rebiotix being explicitly told that they "had the right to use UMN's patents." Rather the question is whether UMN's conduct reasonably led Ferring/Rebiotix to believe that UMN would not assert the UMN patents. *Aukerman*, 960 F.2d at 1028. The record evidence affirmatively supports Ferring/Rebiotix's reliance after the UMN patents issued in 2019. Ferring/Rebiotix's state of mind is further reflected in the fact that when they filed suit, they sought a declaratory judgment against Finch only, and not UMN. (D.I. 1.) [redacted]

[redacted]

Finally, the cases cited by Finch/UMN are inapposite. For example, in *Gasser Chair Co. v. Infanti Chair Manufacturing Corp.*, the accused infringer ignored the patentee's charges of infringement. 60 F.3d 770, 776 (Fed. Cir. 1995); (*see also* D.I. 262 at 17 (citing *Gasser* and stating: "finding that because '[the infringer] ignored [patentee's] charges of infringement because he believed the patent was invalid . . . [the infringer] totally failed to show that he acted in reliance on supposed action of [patentee] rather than a business judgment.'")). Here, however, it is undisputed that the parties had no discussions about the UMN patents prior to Ferring/Rebiotix filing suit. (*See, e.g.*, D.I. 10 at ¶ 5; D.I. 30 at ¶ 6.) Similarly, unlike in *Hemstreet v. Computer Entry Systems Corp.*, there is not a total absence of evidence that the accused infringer (here, Ferring/Rebiotix) relied on actions by the patentee (here, UMN) to reasonably conclude the patents would not be enforced. 972 F.2d 1290, 1294-95 (Fed. Cir. 1992). Rather, the evidence taken as a whole would allow a reasonable fact finder to conclude that there was reliance.

Accordingly, a reasonable fact finder could conclude that Ferring/Rebiotix relied on UMN's misleading course of conduct to conclude that UMN would not assert the UMN patents.

c. A reasonable fact finder could conclude that, as a result of their reliance, Ferring/Rebiotix suffered prejudice.

Finally, as a result of Ferring/Rebiotix's reliance, Ferring/Rebiotix would be prejudiced if UMN is now allowed to assert infringement of the UMN patents. This Court is intimately familiar with pharmaceutical patent litigation, and the costs associated with pharmaceutical drug development. For REBYOTA, those costs include the formulation development (which was

complete by 2013), the costs to run and complete two Phase II and one Phase III clinical trials, to prepare and submit the Biologics License Application ("BLA"), and, because REBYOTA is the first microbiota product to be approved by the FDA, the costs associated with preparing for and participating in a nearly eight hour advisory committee meeting with the FDA.

David Bell, serving as a corporate witness for Ferring/Rebiotix, testified that non-development costs for REBYOTA "[f]or 2020 through approval" were [redacted] Ex. J at 44:16-22. [redacted]. *Id.*at 182:24-185:1. Similarly, for January to March 2023 (launch was in January 2023), expenses associated with REBYOTA were [redacted]. Ex. K at FER_RBX02989030, -032. These expenses, in addition to the above, show that Ferring/Rebiotix have expended significant capital and effort in developing the marketplace for microbiota products, at least in part in reliance on their understanding that UMN would not assert the UMN patents.

E. Conclusion

For the foregoing reasons, Ferring/Rebiotix oppose Finch/UMN's Summary Judgment Motion and respectfully request that the Court:

- Deny the motion as moot with respect to the Finch patents, and
- Deny the motion with respect to the UMN patents because a reasonable fact finder could determine that Ferring/Rebiotix have shown by a preponderance of the evidence that Finch/UMN are equitably estopped from enforcing the UMN patents.

IV. THE COURT SHOULD DENY FINCH/UMN'S *DAUBERT* MOTION

A. Summary of Argument

This Court should deny Finch/UMN's *Daubert* Motion because it erroneously characterizes the testimony that Ferring/Rebiotix propose expert Kurt R. Karst will offer as

entirely legal in nature. But it is not. Federal Rule of Evidence 702 permits expert testimony on topics involving "scientific, technical, **or other specialized knowledge**." FED. R. EVID. 702 (emphasis added). And there can be no dispute that Mr. Karst has specialized knowledge on FDA practices and the impact of FDA decisions regarding drug approval and labeling. His expertise will help the trier of fact. Finch/UMN have made clear that they intend to propose to the jury an alleged infringing use that was unequivocally rejected by the FDA during the REBYOTA approval process. *See* Ex. L ¶ 69. Indeed, the label explicitly says REBYOTA is not approved to treat infection, as required by many of the asserted claims. Mr. Karst's opinions will help the jury understand the meaning of the label and its significance for how REBYOTA may be prescribed. He is highly qualified to provide these opinions, having handled thousands of FDA matters on behalf of hundreds of clients on issues involving labeling, FDA submissions, and approvals. Mr. Karst has been retained as an expert many times for this reason and has previously given testimony to a jury on similar issues. (D.I. 265, Ex. 25 at pdf page 5 ("*GlaxoSmithKline LLC et al. v. Teva Pharms., USA, Inc*., 1:14-cv-00878-LPS-CJB (D. Del.)").) Not once has he been excluded. The jury in this case would benefit from being able to hear from Mr. Karst on exactly how FDA's rejection of Finch/UMN's alleged infringing use affects whether infringement is even possible for many of the asserted claims.

B. Statement of Facts

Finch/UMN's expert, Dr. Neil Stollman, opines that REBYOTA is indicated for ***treating*** recurrence of *C. difficile* infection (rCDI). Ex. L ¶ 69. Dr. Stollman bases his opinion on early versions of REBYOTA prescribing information, Ferring/Rebiotix's promotional materials, REBYOTA clinical studies, and REBYOTA's original Orphan Drug Designation. *Id*. ¶¶ 70, 73, 80, 103. Dr. Stollman also opines that, despite the Limitation of Use added by FDA, use of REBYOTA for treatment of CDI is not an "off label use." *Id*. ¶ 99. Finch/UMN advance the

position articulated by Dr. Stollman to argue that REBYOTA meets certain elements of the claims asserted in this case related to the treatment (rather than prevention) of rCDI. Finch/UMN's position plainly conflicts with REBYOTA's label and the FDA-approved indication.

In rebuttal, Mr. Karst first opines that FDA practice recognizes a clear distinction between treatment and prevention. (D.I. 265, Ex. 34 at Section VII.A.) Mr. Karst, relying on his specialized knowledge of FDA process and procedure, explains that "[g]iven their distinct nature, FDA often, when issuing guidance to regulated industry on the development of products intended for various diseases or conditions. . . distinguishes between treatment and prevention claims and the types of studies and data needed to support each type of indication and labeling claim." (*Id.* ¶ 61.)

Second, to rebut Dr. Stollman's assertion that the purpose of REBYOTA is to treat CDI, Mr. Karst explains that "FDA would not have licensed REBYOTA for the treatment of CDI when, in fact, the Agency determined that the data and information submitted in BLA 125739 supported only the proposed prevention indication." (*Id.* ¶ 63.) [redacted] (*Id.* ¶¶ 65-67.) Based on his extensive experience with FDA approval process and labeling procedures, Mr. Karst explains the import of this limitation and details how Dr. Stollman's opinions "are irrelevant to the indication for which REBYOTA is licensed[.]" (*Id.* ¶ 74.) Mr. Karst further explains that Dr. Stollman's attempt "to impute an rCDI treatment indication to [REBYOTA's] clinical trial design labeling statements is unfounded." (*Id.* ¶ 72.)

Finally, Mr. Karst addresses Dr. Stollman's reliance on REBYOTA's early orphan drug designation, explaining "[t]he fact that OOPD initially designated REBYOTA for a treatment

disease/condition and later found sufficient grounds to amend the orphan drug designation to a prevention disease/condition shows that treatment and prevention are, in fact, significantly different from one another." (*Id*. ¶ 79.)[3]

C. Legal Standard

Federal Rule of Evidence 702 allows a witness to testify as an expert if "(a) the expert's scientific, technical, **or other specialized knowledge** will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case." FED. R. EVID. 702 (emphasis added). The Third Circuit recognizes a "liberal policy of admissibility" for Rule 702 testimony. *Pineda v. Ford Motor Co*., 520 F.3d 237, 243 (3d Cir. 2008) (cleaned up). While an expert may not usurp the role of the judge or jury, an expert's opinion may be relevant to the factual aspects of the analysis leading to a legal conclusion. *See Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006). "'[T]he question of whether the expert is credible or the opinion is correct is generally a question for the fact finder, not the court.'" *Bayer HealthCare LLC v. Baxalta Inc.*, No. 16-CV-1122-RGA, 2019 WL 330149, at *1 (D. Del. Jan. 25, 2019) (Andrews, J.) (quoting *Summit 6, LLC v. Samsung Elecs. Co., Ltd.*, 802 F.3d 1283, 1296 (Fed. Cir. 2015)). Indeed, "'[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means

[3] Mr. Karst does not opine on the ultimate issue of whether REBYOTA infringes the treatment claims, leaving that issue for another expert. However, Mr. Karst's opinion supports why, based on the label, this Court should grant summary judgment that these claims cannot be infringed. (*See* D.I. 258 at 24-26.)

of attacking shaky but admissible evidence.'" *Id.* (quoting *Daubert v. Merrell Dow Pharms.*, 509 U.S. 279, 596 (1993)).

D. Argument

1. Mr. Karst is offering opinions about FDA process and procedure based on his specialized knowledge.

Finch attempts to characterize Mr. Karst's opinions as solely legal in nature. They are not. Instead, Mr. Karst, relying on his specialized knowledge with FDA proceedings, offers opinions as to FDA's approval process and procedures and the meaning of prescription drug labels, including their importance in the relevant marketplace. Courts have repeatedly recognized that this type of testimony can be helpful to the trier of fact. *Par Pharm., Inc. v. Hospira, Inc.*, No. 17-944-JFB-SRF, 2019 WL 2396748, at *3 (D. Del. June 6, 2019) (collecting cases).

For example, in *Par Pharmaceutical*, a Hatch-Waxman case, the Court denied a motion to exclude expert testimony from a regulatory consultant regarding the FDA approval process and effect of defendant's statements and actions before the FDA. *Id.* at *1, *3. The Court noted that "[p]roviding the context for FDA regulations governing drug approval can be relevant and proper expert testimony" to aid the fact finder in its understanding of FDA approval processes. *Id*. at *3. Similarly, in a products liability action, the Western District of Pennsylvania denied a motion to exclude expert testimony related to the "general FDA regulatory scheme," "FDA's requirements for labeling[,] and the adequacy of [] warnings and labels[,]" explaining that such opinions are distinguishable from improper legal opinions, such as whether defendant complied with FDA regulations. *Rowland v. Novartis Pharms. Corp*., 9 F. Supp. 3d 553, 561-62 (W.D. Pa. 2014); *see also Reece v. Astrazeneca Pharms., LP*, 500 F. Supp. 2d 736, 743-44 (S.D. Ohio 2007) (permitting expert testimony regarding FDA requirements for approval, labeling, advertising, and marketing of pharmaceutical and medical products, as well as the issues that the

FDA considers in the development of product labeling and marketing information). Such testimony is particularly warranted where Finch/UMN assert claims based on treatment of rCDI, an indication that was specifically excluded from the FDA-approved label. *See, e.g.*, *Rowland*, 9 F. Supp. 3d at 561 ("[w]here . . . plaintiffs have asserted claims based on violations of FDA regulations, . . . courts have routinely allowed [expert testimony] as to the general FDA regulatory scheme . . . and [FDA] regulations regarding new drug application, approval, monitoring, and labeling."). Even to the extent Mr. Karst applies FDA regulations in arriving at his opinions, testimony that "[f]irst . . . sets forth the relevant [FDA] regulations[, then] applies these regulations to the facts . . . at hand" is not impermissible. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.,* No. 2:18-CV-01509, 2021 WL 3617152, at *10 (S.D. Ohio Aug. 16, 2021).

Finch/UMN attempt to portray statements from Mr. Karst's expert report as legal opinions by quoting extensively from the background section of his report and emphasizing particular words in Mr. Karst's statements. (*See, e.g.,* D.I. 262 at 22-24.) These efforts miscast his opinions. When read in context, it is clear that, although Mr. Karst's opinions are informed by the "relevant [FDA] regulations" and laws, their core focus is the "appli[cation]" to REBYOTA and the impact of FDA's procedure and labeling decisions. *See In re Davol*, 2021 WL 3617152, at *10. Such approach is not markedly different from a technical expert first providing the underlying legal standards for infringement or validity, then applying them to the facts of the case. For instance, in paragraph 63 of his report, Mr. Karst, relying on FDA practice and guidance that "[p]revention and treatment are wholly different claims," concludes that "FDA *would not have licensed* REBYOTA for the treatment of CDI when, in fact, the Agency determined that the data and information submitted in BLA 125739 supported only the proposed

prevention indication." (D.I. 265, Ex. 34 ¶ 63 (emphasis added); D.I. 262 at 23.) As another example relied on by Finch/UMN, Mr. Karst sets forth the relevant portion of "21 C.F.R. § 316.26" in paragraph 78 of his report. (D.I. 265, Ex. 34 ¶ 78; D.I. 262 at 24.) Then, relying on his specialized knowledge of FDA practice and procedure to explain the significance of statements made during the FDA approval of REBYOTA, Mr. Karst concludes in paragraph 79 that: "[t]he fact that OOPD initially designated REBYOTA for a treatment disease/condition and later found sufficient grounds to amend the orphan drug designation to a prevention disease/condition *shows that treatment and prevention are, in fact, significantly different from one another*."[4] (D.I. 265, Ex. 34 ¶ 79 (emphasis added).)

Nor is the deposition testimony relied on by Finch/UMN availing, as the very quotes Finch/UMN cite show Mr. Karst is offering opinions as a "clinical" and "practical" matter. (D.I. 262 at 24 (citing D.I. 265, Ex. 35 at 93:12-16, 95:11-18); *see also* D.I. 265, Ex. 35 at 92:21-93:5 ("My expert report is providing on [sic] opinion on what–as legal and **clinical matters** because the two are quite inextricably linked–what is appropriate to include in labeling based on what the data–based on the data submitted to the Agency supporting the proposed labeling for the approved product *and providing such opinions in response to the opinions that Dr. Stollman provided*." (emphasis added)).) Mr. Karst's opinions are precisely the type of opinions previous courts have found helpful to aid the trier of fact in "understanding . . . FDA approval processes." *Par Pharm., Inc.*, 2019 WL 2396748, at *3. The benefit of Mr. Karst's testimony is particularly

[4] Finch/UMN argue in a footnote that FDA custom and practice opinions are not relevant. (D.I. 262 at 29 n.11.) But *AstraZeneca LP v. Apotex, Inc*. is inapposite, as its holding relates to statements by FDA regarding infringement of the patent-at-issue. 633 F.3d 1042, 1061 (Fed. Cir. 2010).

important in light of Finch/UMN's reliance on an alleged infringing use already rejected by FDA and because it responds to the opinions proffered by Finch/UMN's expert, Dr. Stollman.

Two of Finch/UMN's cited cases support a party's ability to offer expert testimony on practices and procedures of regulatory agencies. *See, e.g.*, *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1364 n.6 (Fed. Cir. 2008) (noting that the court did not doubt the expert could testify as to patent office procedures and stating "[o]ur holding . . . is not a general proclamation as to the admissibility of expert testimony on legal questions."); *Berckeley*, 455 F.3d at 216-18 (finding that expert testimony from a former SEC lawyer regarding customs and business practices in the securities industry would be helpful to the jury). And the main case on which they rely—*Takeda Pharmaceuticals USA, Inc. v. Par Pharmaceutical Cos.*, No. 13-1524-SLR, 2015 WL 13877466 (D. Del. Nov. 24, 2015)—is distinguishable. In *Takeda*, the Court excluded expert testimony regarding whether plaintiff properly listed certain patents in the ORANGE BOOK for reasons that are not present here: (1) the expert's report offered an opinion on an ultimate legal issue; (2) the expert was not qualified to opine on FDA regulatory procedures/practices; (3) the expert's report was directed to legal interpretation of FDA regulations, not custom and practice; and (4) the expert's report addressed a "hypothetical FDA issue" (*i.e.*, what a generic drug label would include). *Id.* at *1. Here, Mr. Karst sets out the applicable FDA regulations and history, which Finch/UMN do not contend are incorrect, and he does not offer an opinion on an ultimate legal issue (*i.e.*, whether REBYOTA infringes the asserted claims). Ex. M at 100:24–101:11. Moreover, he is highly qualified to opine on FDA practices and the importance of approved drug labeling, as demonstrated by his long history of representing clients and regularly speaking and publishing on these issues. (D.I. 265, Ex. 25.) Unlike *Takeda*, Mr. Karst will offer opinions about FDA practice and procedure and the meaning

of approved labels, not solely legal opinions, such as whether Ferring/Rebiotix have complied with FDA regulations. And, of course, he will offer opinions related to an already-approved—not hypothetical—label. One final point bears noting. In *Takeda*, the Court emphasized that the party seeking exclusion would not be calling its own expert to opine on the same issues. 2015 WL 13877466 at *1. But, here, Finch/UMN are offering Dr. Stollman to opine on the precise issues on which they seek to exclude Mr. Karst.[5]

2. Mr. Karst is qualified to offer expert testimony.

Finch/UMN argue that Mr. Karst is not qualified to offer any opinion testimony because he lacks technical expertise. (D.I. 262 at 29-30.) This analysis is misplaced. Finch/UMN's argument is premised on a misreading of FRE 702, limiting expert testimony solely to scientific or technical issues. *Id.* But the clear text of FRE 702 confirms that a witness may testify as an expert if "the expert's scientific, technical, **or other specialized knowledge** will help the trier of fact to understand the evidence or to determine a fact in issue." FED. R. EVID. 702 (emphasis added). Finch/UMN do not dispute that Mr. Karst has specialized knowledge about FDA practice and interpretation of approved drug labels. Nor could they, given Mr. Karst's significant experience with these issues. Thus, Finch/UMN's position lacks merit. *See Shire Viropharma Inc. v. CSL Behring LLC*, No. CV 17-414, 2021 WL 1227097, at *5 n.3 (D. Del. Mar. 31, 2021) ("As this experience directly relates to the issues here and qualifies him—under *Daubert*'s liberal standards—to opine on FDA regulatory issues, I find no merit to Plaintiff's cursory challenge to his qualifications.").

[5] To the extent the Court agrees with Finch that the issues on which Mr. Karst seeks to offer testimony are legal opinions, the parties should be permitted to propose jury instructions on the relevant FDA regime.

Finch/UMN's attempt to characterize Mr. Karst as an infringement expert does not help their argument. He explicitly stated that he is not providing infringement opinions. *See* Ex. M at 54:13-18 ("So when we start talking about patent infringement, **not only is it outside the scope of my report**, but again, as we've established, I'm not a patent attorney able to render, you know, opinions on infringement matters." (emphasis added)). Instead, as Finch/UMN cannot dispute, Mr. Karst is qualified to opine on the import of FDA drug approval processes and labeling. (*See* D.I. 262 at 21.) Unlike *Sundance, Inc.*, where the expert's experience with patent office practice and procedure was not related to the technical issues on which he sought to opine, 550 F.3d at 1360-61, Mr. Karst's experience with FDA's process and procedure is directly relevant to the issues on which Ferring/Rebiotix propose he testify, including the meaning of REBYOTA's approved label and the importance it has in the relevant marketplace. His testimony will be particularly helpful to the trier of fact here, as Finch/UMN propose an off-label use case for REBYOTA—that it is to be used for "treatment" instead of "prevention"—and the jury will be aided by understanding the import of the FDA's rejection of that use case and "Limitation of Use" instruction in the label that excludes it.

E. Conclusion

For these reasons, Ferring/Rebiotix respectfully request that the Court deny Finch/UMN's motion to exclude Mr. Karst's testimony at trial.

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